## **EX PARTE OR LATE FILED**



DOCKET FILE COPY ORIGINAL

IEEE

### STANDARDS COORDINATING COMMITTEE 28 **NON-IONIZING RADIATION**

FEDERAL COMMUNICATIONS COMMISSION OFFICE OF THE SECRETARY

April 21, 1994

Chair

Dr. Thomas F. Budinger University of California, at Berkeley (415) 486-5435

Vice Chair

Dr. A. William Guy University of Washington Retired (206) 486-6439

IEEE Standards Staff Lieison

Mr. John Parisi IEEE Standards Activities (908) 562-3810

Executive Secretary

Dr. John M. Osepchuk Raytheon Company (617) 860-3041

Subcommittee Chairs:

SC-1

Techniques, Procedures and Instrumentation

Dr. Howard Bassen

Ctr. Devices & Radiological Health, FDA

(301) 443-3840

SC-2

Terminology and Units of Measurements Mr. Richard A. Tell

Richard Tell Assoc., Inc. (702) 645-3338

Safety Levels with Respect to Human Exposure, 0-3 kHz

Dr. John A. Bergeron G. E. Corp. R & D (518) 387-6350

Mr. William Feero Electric Research and Management, Inc.

(814) 466-3031

Safety Levels with Respect to Human Exposure, 3kHz-300GHz

Dr. Eleanor R. Adair J.B. Pierce Foundation Labs (203) 562-9901 Ext. 218

Dr. Om P. Gandhi University of Utah (801) 581-7743

Safety Levels with Respect to **Electro-Explosive Devices** 

Mr. Thomas P. Stanley, Chief Engineer Office of Engineering and Technology Federal Communications Commission Mail Stop 1300 1919 M Street, N.W. Washington, DC 20554

Dear Mr. Stanley:

In the matter of Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, ET Docket No. 93-62, please find enclosed Replace Comments of the IEEE-SCC28. These comments were prepared by members of the Interpretations Working Group and endorsed by a consensus of Subcommittee 4.

Sincerely,

R. C. Petersen

Secretary, Subcommittee 4

**Enclosure** As above

Copy to

E. R. Adair

T. F. Budinger

O. P. Gandhi

A. W. Guy

J. M. Osepchuk

J. Parisi - IEEE

No. of Copies rec'd

ListABCDE

No. of Copies List ABCDE

# Before the FEDERAL COMMUNICATIONS COMMISSION Washington, D. C. 20554

In the Matter of	)
·	)
Guidelines for Evaluating the	)
Environmental Effects of	) ET Docket No. 93-62
Radiofrequency Radiation	)

# REPLY COMMENTS OF THE IEEE - SCC 28 PREPARED BY THE SUBCOMMITTEE 4 WORKING GROUP ON INTERPRETATIONS AND ENDORSED BY A CONSENSUS OF SUBCOMMITTEE 4

#### **PREFACE**

It is appropriate, as an introduction to this reply, to discuss the committee approach to the setting of standards. Virtually all standards for human exposure to nonionizing electromagnetic fields have derived from the collective thinking of groups of individuals who play active roles in this specialized technical area. As examples, the IEEE, NCRP and ICNIRP standards-setting committees all function through the contributions of volunteer technical experts who are specialists in a variety of disciplines directly related to assessment of the biological effects and potential hazards of exposure to these fields.

In the IEEE, standards documents are developed within the Technical Committees of the various IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Board. Members of these committees, often non-IEEE members, serve voluntarily and without compensation. The standards developed through this process represent a consensus of the broad expertise represented on individual committees; This is one of the strengths of the IEEE process in the development of safety levels with respect to human exposure to radiofrequency fields.

The fact that the IEEE C95.1-1991 standard, adopted by ANSI in 1992, is a consensus standard means, in practice, that every effort is made to gain unanimous agreement of committee members prior to finalization. Dissenting votes, usually cast on specific aspects of the standard rather than the entire document, are addressed by a special committee in the hope of satisfying the dissenting members. During the recent revision process of ANSI C95.1-1982 by SC-4 of IEEE SCC 28, 86% of those members casting ballots approved the final version of the extensively-revised standard.

The members of SC-4 represented a wide range of technical expertise including medicine, biology, engineering and physical sciences. The ANSI/IEEE C95.1-1992 document describes in detail how this expertise was used to evaluate the biological database, dosimetry, statistical treatments and exposure risk, in addition to the drafting and refinement of the text. In January 1990, at the time of the final balloting, many of the SC-4 members were also members of IEEE and two-thirds were members of the Bioelectromagnetics Society. The IEEE process, as outlined above, achieved a standard with broad scientific support. At the time of balloting, SC-4 consisted of 125 individuals with the following affiliations:

Affiliations of Members of the IEEE Standards Coordinating Committee, Subcommittee IV on Non-ionizing Radiation Hazards

Affiliation	Number	Percentage
Research: University	37	29.6
Nonprofit	8	6.4
Military	15	12.0
Government	30	24.0
Industry	12	9.6
Industry - Consulting	4	3.2
Government - Administration	5	4.0
General public and independent consultants	14	11.2
Total	125	100.0

Historically, the several ANSI guidelines for the safe exposure of human beings to radiofrequency fields have been the most innovative and have become the standard that others have followed. For example, the ACGIH has patterned their standards after C 95.1-1982 and C95.1-1991 and the NCRP patterned their 1986 guidance after C95.1-1982. Further, the three proposals for Federal guidance offered in 1986 by the EPA were all based on C95.1-1982. Even the standard recently promulgated in the United Kingdom by the NRPB bears a striking resemblance to ANSI/IEEE C95.1-1992, including the characterization of the two tiers in terms of environment rather than population type.

As stated in the Comments of the IEEE SCC 28, submitted in the referenced matter on November 4, 1993, it is important to recognize that ANSI/IEEE C95.1-1992, like its ANSI predecessors, must be considered a "living document". It is designed to be continually in the process of revision and refinement as additional research reports appear in the archival literature.

### REPLY TO THE COMMENTS OF THE EPA

In their Comments submitted to the FCC in the referenced matter, the United States Environmental Protection Agency (EPA) made certain statements and recommendations to which SC-4 of IEEE SCC28 here respond. The following matters are discussed in some detail in the sections below:

- 1. Increased Maximum Permissible Exposure (MPE) at high frequencies.
- 2. Controlled/uncontrolled environments <u>vs</u> occupational/general public exposure to characterize 2 tiers.
- 3. ANSI/IEEE C95.1-1992 is a "thermally based" standard.
- 4. ELF amplitude modulation of RF is not considered.
- 5. Recommendation that guidelines in NCRP Report No. 86 be adopted instead of ANSI/IEEE C95.1-1992
- 1. Increased Maximum Permissible Exposure (MPE) at high frequencies.

  The EPA comments recommend that the FCC adopt the guidelines published by the National Council on Radiation Protection and Measurements (NCRP) published in their report entitled "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields (NCRP 1986)". The EPA comments state that the NCRP exposure criteria are "more protective" at higher frequencies than are the ANSI/IEEE C95.1-1992 limits.

The NCRP limits are 5 and 1 mW/cm<sup>2</sup> for workers and the general public, respectively; the associated averaging times are 6 and 30 minutes respectively.

While SCC-28 recognizes the concern of the EPA over an increase in the MPE of ANSI/IEEE C95.1-1992 from that of ANSI C95.1-1982 at these frequencies, we refer the FCC to the considerable discussion in the ANSI/IEEE C95.1-1992 Rationale concerning thresholds, safety factors, penetration depth, surface heating, and averaging time to support 10 mW/cm<sup>2</sup> MPE at frequencies where the penetration depth is similar to that of visible and infrared radiation and where surface effects predominate. For short exposure durations, ANSI/IEEE 1992 is actually more protective than NCRP 1986 at the higher microwave frequencies because of the frequency dependence of the specified averaging time (10 seconds at the highest frequency). The ANSI/IEEE 1992 MPEs are also consistent with an extensive established infrared database and with the infrared MPEs in well-established laser safety standards (ANSI Z136.1-1993).

2. <u>Controlled/uncontrolled environments vs occupational/general population exposure to characterize two tiers.</u> In their comments to the FCC, the EPA objects that the two tiers of the ANSI/IEEE 1992 guideline are labeled "controlled environment" and "uncontrolled environment" and

recommends the terms "occupational" and "general population" be used instead, as is the case with NCRP, 1986. The EPA bases this recommendation on the belief "that the general population has groups of individuals particularly susceptible to heat" and should be afforded the greater protection of a lower safety guideline. This view is supported by a citation of the NCRP statement (NCRP, 1986, p. 282) that

"... the population at large ... contains sub-populations of debilitated or otherwise potentially vulnerable individuals for whom there is presently inadequate knowledge to set firm standards. For example, the sensitivity of aged individuals, of pregnant females and their concepti, of young infants, or of chronically ill persons is not known."

Apart from the fact that it is unknown whether certain subgroups of the population may be more at risk than others, it is our view that use of the "occupational" and "general population" designations provides even less certainty than use of "controlled" and "uncontrolled" environments. For example, under the uncontrolled category, ANSI/IEEE-1992 includes office workers in an industry that employs radiofrequency radiation as an important element of its business. Indeed, the definition of the uncontrolled environment (ANSI/IEEE-1992, p.12) specifies that the exposure may be in a workplace as well as in living quarters. Under NCRP-1986, these individuals would be "workers" and the higher MPEs would apply. It should be clear that no home, hospital, nursing home, school, playground, park, department store, or other gathering place where people are likely to stay for extended periods of time could be classified as a "controlled environment".

While SCC-28 was the first to recognize the usefulness of the concepts of "controlled" and "uncontrolled" environments (e.g., to remove any ambiguity in the distinction between those "occupationally" exposed because they are directly involved with the operation of an RF/microwave source at some facility and those who are "occupationally" exposed only because they are employed at the same facility), other organizations are also recognizing the usefulness of these concepts. For example, "controlled" and "uncontrolled" environments, rather than "occupational" and "general population" exposures, are now being used by the European Committee for Electrotechnical Standardization (CENELEC) in their latest draft (August 12, 1993) of the report CLC/SCIIIB, Human Exposure to Electromagnetic Fields: 10 kHz - 300 GHz. The CENELEC definitions of the two environments are entirely consistent with the definitions in ANSI/IEEE C95.1-1992.

The EPA also recommends that a "general population" classification be applied to the use of low power devices unless the user is operating the device as a concomitant of employment. This view betrays a lack of understanding and appreciation of the public's use of the radiofrequency spectrum for other than commercial purposes. Indeed, the NCRP guidelines

state:

"... in the case of individuals in the general population who use radio emitters of various kinds (e.g., hand-held transceivers, remote control devices, etc.) the exposures of these individuals may be greater than the values recommended for the general population. Use of such devices is permitted, as a personal decision by the individual, provided that the devices are designed and used as designed so that the exposure of the individual does not exceed the recommended occupational guidelines and provided that, in using the devices, the individual does not expose other persons above the general population guidelines."

There are approximately 665,000 licensed radio amateurs in North America who use radio transceivers and transmitters with average input powers (to the antenna) varying from 1 to 1000 watts. There are probably many more citizens-band enthusiasts and marine radio users who use radio transmitting equipment varying in input power from 0.05 to 6 watts. Many of the transceivers used are either hand-held portable or mobile radios. The NCRP permits the use of such devices, as a personal choice by the user, provided the devices are so designed that exposure of the individual does not exceed the limits for occupational exposure. The basis for the NCRP exclusion of those in the general population who choose to use such devices is that they are aware of their exposure, they have control of the exposure and the duty cycle is so low that an imposed 1/5 reduction of the exposure from occupational levels is unnecessary. Since the devices are frequently used in emergency communications relating to the safety of the user or members of the public, the benefits to the general public in not limiting the power of such devices far outweigh any increased risks from exposure of the user at occupational levels.

Virtually all hand-held communications devices operate in the range of 0.1 to 5 watts, which is well within the ANSI/IEEE low power exclusion limit for the controlled environment. An imposed restriction of the power of such devices, which members of the general population use by choice, could result in diminished communications range and increased risk to the general public, especially following criminal activities, accidents or natural disasters.

As do the NCRP guidelines, the ANSI/IEEE-1992 guidelines also recognize the need for those who knowingly choose to operate hand-held radio transceivers to be classified as belonging to the controlled environment. It is important to note that both the NCRP and ANSI/IEEE guidelines would classify the use of a cellular telephone to be governed by the guidelines of the upper tier. Like the hand-held transceivers, the cellular telephone has become important to the safety and well being of the public in emergency situations and many people buy them only for that purpose.

- 3. ANSI/IEEE C95.1-1992 is a "thermally-based" standard. The EPA comments to the FCC assert many times that the ANSI/IEEE-1992 guidelines ignore athermal biological effects and are based only on harmful thermal effects. However, it is clearly stated in the standards document that in the literature review that preceded the establishment of the guidelines, no preconceived assumptions were made concerning mechanisms, thermal or athermal. The literature that formed the 4 W/kg basis for the guidelines had to satisfy several strict criteria: that any observed effects had been independently replicated; that such effects had been demonstrated in several species and under different field conditions; and that the effects were shown to be harmful. The disruption of food-motivated behavior in the presence of radiofrequency fields, by several animal species and under widely-varying field parameters, was the effect that satisfied these criteria at the lowest specific absorption rate (SAR ~ 4 W/kg). Consensus for approval of safety guidelines by SC-4 would have been impossible without such criteria. That behavior disruption under these conditions could be accompanied by a rise in body temperature is incidental to the fundamental observation. Since the promulgation of ANSI C95.1-1982, nearly all of the safety guidelines in the Western world have been based on behavior disruption in laboratory animals, including NCRP, 1986.
- 4. ELF amplitude modulation of RF is not considered. In its comments to the FCC, the EPA points out that the NCRP, 1986 guideline recognizes that there may be important consequences of ELF-modulated RF carriers. NCRP requires: "If the carrier frequency is modulated at a depth of 50% or greater at frequencies between 3 and 100 Hz, the exposure criteria for the general population shall apply to occupational exposures" (NCRP Report No. 86, p. 286).

While the EPA correctly points out that the NCRP modulation provision for workers "... is unique; no other exposure guideline contains such a provision" (EPA comments to FCC, page 9), the NCRP report also contains the statement, "It is not known whether these effects [of RF fields under low-frequency modulation] pose a risk to health. .." (ibid.). Similarly, the WHO/IRPA Task Group on Electromagnetic Fields points out in its 1993 Environmental Health Criteria 137 Report, "(t)he biological significance and possible adverse health impact, if any, of the reported effects cannot be determined at this time." SC-4 agrees. There is no compelling evidence that would indicate that ELF-modulated RF fields pose a hazard to human health. The absence of such evidence is the reason why the ANSI/IEEE standard does not contain provisions for ELF-modulated RF.

Furthermore, the EPA itself states on page 5 of its comments that "While studies continue to be published describing biological responses to non-thermal ELF-modulated RF radiation, the effects information is not yet sufficient to be used as a basis for exposure criteria to protect the public against

adverse human health effects." This is entirely consistent with ANSI/IEEE C95.1-1992 where it is stated, "Research on the effects of chronic exposure and speculations on the biological effects of nonthermal interactions have not yet resulted in any meaningful basis for alteration of the standard. It remains to be seen what future research may produce for consideration at the time of the next revision of the standard."

5. Recommendations that guidelines in NCRP Report No. 86 be adopted instead of ANSI/IEEE C95.1 - 1992. The EPA, in its comments to the FCC, has expressed confidence in the ANSI/IEEE-1992 limits for induced and contact RF currents, for the frequency range of 300 kHz to 100 MHz, to protect against shock and burn. It is surprising that the EPA did not also endorse the tabulated MPEs because, with the exception of the increased MPEs and single tier at the higher microwave frequencies and an expanded range of frequencies covered by ANSI/IEEE-1992 relative to NCRP, 1986, the field limits in the broad frequency range at which humans are resonant are essentially the same in both standards. In addition, both standards are based on the use of SAR as the fundamental dosimetric parameter, the same criterion biological effect (behavior disruption) and the same safety factors to define the two tiers. It appears that the differences between the two standards are based more on the explanation of the rationale and the interpretation of the scientific uncertainties than on the actual limits recommended. true even of the meaning of "athermal" as applied to the scientific underpinning of a guideline. In point of fact, some of the ANSI/IEEE-1992 standard is based on avoidance of shock. The excitation of muscle and nerve is not normally considered a thermal effect but proceeds in accordance with known and well-established physical and chemical principles. Shock is also well accepted as a basis of inferring risk to health.